

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2151-2200

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *December 22, 1947.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2151. Misbranding of Yuk-Air Compound. U. S. v. Albert Hassman. Motion to dismiss indictment denied. Plea of guilty. Fine, \$800 and costs. (F. D. C. No. 14285. Sample Nos. 49064-F, 50177-F, 59721-F.)

INDICTMENT RETURNED: February 13, 1945, Northern District of Ohio, against Albert Hassman, president of Universal Drug Products, Inc., Cleveland, Ohio.

ALLEGED SHIPMENT: Between the approximate dates of February 5 and 18, 1944, from the State of Ohio into the States of Michigan, Indiana, and West Virginia.

PRODUCT: Analysis disclosed that a portion of the *Yuk-Air Compound* was a colorless liquid consisting essentially of oil of turpentine and that the remainder of the product was a yellow liquid, some consisting of oil of eucalyptus and some consisting essentially of oil of eucalyptus and oil of turpentine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article, in accompanying circulars entitled "*Yuk-Air Daily, Vol. 1, Universal Edition, 1944,*" and in accompanying placards were false and misleading since they represented and suggested that the article would be safe for use on every part of the body; that it would be appropriate for use generally as

* For new drug shipped without effective application, see No. 2151; failure to bear a label containing the place of business of the manufacturer, packer, or distributor, No. 2200; inconspicuousness of required label information, No. 2184; cosmetics, subject to the drug provisions of the Act, Nos. 2167, 2184.

a massaging and rubbing oil and could be used and rubbed on the body freely without fear of irritation of any kind; that it would be an efficacious treatment for stiff joints; that it would be efficacious in the cure, mitigation, treatment, and prevention of colds, influenza, coughs, asthma, sinus, and catarrhal conditions; that it would be efficacious in the mitigation and treatment of disease and disease conditions accompanied by fever; and that it would be efficacious in dissipating fever and restoring normal body temperature. The article would not be safe for use on every part of the body; it would not be appropriate for use generally as a massaging and rubbing oil, and it might cause irritation to the skin when used as directed; and it would not be efficacious for the purposes represented.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage suggested in the labeling, "Eucalyptus Oil * * * Used in * * * Ear Oil" and "It may be used safely on any part of the body," since when used in the ears the article would cause injury.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, against unsafe methods and duration of application, in such manner and form, as are necessary for the protection of users, since its labeling failed to bear warnings against allowing the article to get into the eyes and ears or onto the mucous membrane, and against continued use of the article if excessive irritation should develop, since the article might be harmful to the eyes, ears, mucous membrane, and irritated skin.

Further misbranding, Section 505, the article was a new drug within the meaning of the law in that it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions recommended and suggested in their labeling; and application filed, pursuant to the law, was not effective with respect to the article.

The indictment alleged also that another product, *Sol-A-Min*, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 31, 1947. The defendant's motion to dismiss the indictment having been denied, a plea of guilty was entered and the court imposed a fine of \$1,000, plus costs.

2152. Adulteration and misbranding of procaine hydrochloride solution. U. S. v. A. Pfingst, a partnership, and Ernest Pfingst. Pleas of guilty. Fine of \$500 against both defendants jointly and severally. (F. D. C. No. 14300. Sample Nos. 35041-F, 50281-F.)

INFORMATION FILED: March 7, 1947, Southern District of New York, against A. Pfingst, a partnership, and Ernest Pfingst, New York, N. Y.

ALLEGED SHIPMENT: Between the approximate dates of March 7 and 20, 1944, from the State of New York into the States of Georgia and Pennsylvania.

LABEL, IN PART: "Procaine Hydrochloride Solution 2% with Epinephrin (Pfingst)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since the appropriate use for the article required that it be a sterile product, whereas it was nonsterile and contaminated with living micro-organisms.

Misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage suggested in the labeling, due to the presence of living micro-organisms.

DISPOSITION: May 1, 1947. Pleas of guilty having been entered, the court imposed a fine of \$500 against both defendants jointly and severally.

2153. Misbranding of first aid kits and contents. U. S. v. 15,000, etc. (F. D. C. Nos. 20530, 20531. Sample Nos. 63802-H to 63804-H, incl.)

LIBELS FILED: July 18, 1946, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of May 17 and August 13, 1945, by Burke Drug Supply, from Dayton, Ohio.

PRODUCT: 15,000 complete *first aid kits with contents* and 5,500 *incomplete first aid kits* at New York, N. Y.; also 5,500 vials of *Amphetamine sulfate tablets*, 5,500 vials of *wound tablets*, and 500 vials of *atabrine tablets*, all of which had